California Medical Device Recall Information

Recall Name
Covidien Recalls Monoject Prefill Flush Syringes Due to Sterility Assurance and Quality Control Concerns

Recall Date	Product Description	Recalling Firm	Recall Reason
8/16/13	Monoject prefill flush 12mL Syringes (multiple fill volumes affected): • Monoject 0.9% Sodium Chloride Flush Syringe • Monoject 10 Units/mL Heparin Lock Flush • Monoject 100 Units/mL Heparin Lock Flush	**Covidien** Mansfield, MA	*Possible risk that syringes were not subjected to autoclave sterilization.* *Some syringes also have mismatched caps, labels, and wrapper.*

Recall Class	Product Identification		Distribution	Affected Dates
I	**Product ID**	**Lot #***	**CA**, nationwide	Covidien alerted customers of the recall by letter on 8/16/13.
	8881570121	13A0084N		
	"	13A0094		
	"	13B0364		
	"	13C0504		
	"	13C0514		
	8881570123	13A0084N		
	8881570125	13A0084N		
	8881580121	13A0084N		
	8881580123	13A0084N		
	8881580125	13A0084N		
	8881590121	13A0084N		
	8881590123	13A0084N		
	8881590125	13A0084N		
	"	13D0824N		
	* Lot numbers can be found on the shipper case, carton and individual syringes.			

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

http://www.fda.gov/Safety/Recalls/ucm365577.htm